UNITED STATES DISTRICT COURT EASTERN DISTRICT OF TENNESSEE AT GREENEVILLE

UNITED STATES OF AMERICA,)	
Plaintiff,)	
)	No. 2:13-cr-56
v.)	Judge Greer
)	
ANINDYA KUMAR SEN and)	
PATRICIA POSEY SEN,)	
Defendants.)	

MOTION TO DISMISS

The United States of America hereby moves, pursuant to Fed. R. Crim. P. 48(a), to dismiss the third superseding indictment as to defendants Anindya Kumar Sen and Patricia Posey Sen, and, in support thereof, states as follows:

- 1. Rule 48(a) provides that "[t]he government may, with leave of court, dismiss an indictment, information, or complaint." Fed. R. Crim. P. 48(a).
- 2. In December 2013, a jury convicted the defendants of twenty-nine misdemeanor counts of introducing misbranded drugs into interstate commerce, in violation of 21 U.S.C. § 331(a). (R. 134, Jury Verdict.) Following the entry of judgment in this case, and while the defendants' appeals were pending, the Department of Justice reviewed its charging practices under 21 U.S.C. § 331 in cases involving the interstate distribution of misbranded or adulterated articles. The Department focused on, *inter alia*, the appropriate legal provisions for charging persons who order or purchase such articles for delivery to themselves from a distributor in another state or another country. Although consideration of those issues is still ongoing, the Department ultimately decided not to pursue charges under 21 U.S.C. 331(a) on the facts presented in this particular case.

- 3. Accordingly, in the exercise of prosecutorial discretion, the United States moved the Sixth Circuit Court of Appeals to vacate the defendants' judgments of conviction and to remand for dismissal of the indictment with prejudice. On January 16, 2015, the Sixth Circuit granted that motion, vacated the defendants' convictions, and remanded to this Court. (R. 195, Order.)
- 4. Consistent with its motion in the Sixth Circuit, the United States now asks this Court to dismiss the third superseding indictment with prejudice.¹

Respectfully submitted,

William C. Killian United States Attorney

By: *s/M. Neil Smith*

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¹ The United States does not condone the conduct for which defendants were prosecuted and is currently evaluating whether the defendants' conduct should be prosecuted under a statute other than 21 U.S.C. § 331(a). The record establishes that defendants ordered and administered misbranded chemotherapy drugs at the oncology practice which they operated in Greeneville, Tennessee. Mrs. Sen, as office manager, ordered various chemotherapy drugs from a company based in Canada; within a three-year period, the defendants' practice paid approximately three million dollars for drugs from that company. The drugs themselves were shipped from the United Kingdom, had foreign languages on the labels, and, in some cases, had entirely different names than chemotherapy drugs approved by the U.S. Food and Drug Administration (FDA) for distribution and use in the United States; as such, the drugs were "misbranded" within the meaning of 21 U.S.C. § 352. The evidence also established that the misbranded drugs were fifteen to seventy percent less expensive than FDA-approved drugs, thereby vastly increasing the defendants' profits, since the practice obtained reimbursement from healthcare-benefit programs for the drugs and the administration of the drugs to patients. As this Court previously found, "it is undisputed . . . that Dr. Sen used non-FDA-approved and misbranded drugs in his practice," conduct which "raises serious safety concerns for the public." (R. 175, Memorandum and Order at 2; see also R. 166, Memorandum and Order at 11 (referencing "overwhelming proof" that Dr. Sen "knew, or should have known, that his medical practice was using misbranded and unapproved drugs in violation of the law").) The evidence at trial also amply established that Mrs. Sen knowingly ordered non-FDA-approved drugs "in order to get a better price on the drugs" and thus increase the practice's profit, despite her knowledge that the practice was obligated to administer FDA-approved drugs. (R. 166, Memorandum and Order at 20-21, 28.)

CERTIFICATE OF SERVICE

I certify that on February 9, 2015, this motion was filed electronically, and notice of its filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. Any parties not listed as being served by the Court's filing system will be served by regular United States mail, postage prepaid.

s/ M. Neil Smith

M. Neil Smith

Assistant United States Attorney